FDA 510(k) Premarket Notification

K151567 ENDOPLUS hand-held laparoscopic instruments

CLEARED

Dec 23, 2015
196 days to decision

K151567 · Product code: **HFI** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k151567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator, Culdoscopic (and Accessories) (HFI)
Date received	Jun 10, 2015
Decision date	Dec 23, 2015
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endoplus**
Location	Mundelein, IL, US
Contact	Matthew Gudeman
510(k) history	1 submissions · 1 cleared · 2015-2015